Supreme Court, U.S.
FILED
APR 16 1996
CLERK

Nos. 95-754, 95-886

IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.
Petitioner/Cross-Respondent,

v.

LORA LOHR and MICHAEL LOHR,
Respondents/Cross-Petitioners.

On Writ of Certiorari to the
United States Court of Appeals for the Eleventh Circuit

REPLY BRIEF FOR CROSS-PETITIONERS LORA LOHR AND MICHAEL LOHR

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REPLY BRIEF FOR CROSS-PETITIONERS

Cross-respondent Medtronic, Inc., begins its brief in No. 95-886 claiming that the Lohrs have ignored the text of the Medical Device Amendments ("MDA") and have improperly focused their arguments on the MDA's purposes. That accusation is inaccurate. In meticulous detail, the Lohrs have analyzed the entire MDA (Lohr Open. Br. 2-7), including its preemption language, 21 U.S.C. 360k (*id.* at 16-27), its "savings" provision, 21 U.S.C. 360h(d) (*id.* at 27-28), the 510k "substantial equivalence" process (*id.* at 34-38), and the body of regulations and rulings issued by the Food and Drug Administration ("FDA") concerning the MDA's preemptive reach. *Id.* at 39-41; *see also* Brief of Respondents in No. 95-754 ("Lohr Resp. Br.") at 6-12, 15-37.

Medtronic is correct, however, that the parties "have taken two markedly different approaches" to this case. Med. Resp. Br. 1. Medtronic claims that the MDA preempts all state medical device law—*even state law based on the same substantive standards as federal law.* *Id.* at 38-49. In contrast, the Lohrs, joined by the Solicitor General, maintain that had Congress wanted to eliminate state law entirely it would have said just that, rather than what it did say: that state law is preempted only where it is "different from, or in addition to" federal law. 21 U.S.C. 360k(a). Similarly, Medtronic bases its preemption claim on general federal regulations that are entirely consistent with the Lohrs' state-law claims and on a grab-bag of *potential* MDA enforcement mechanisms, some of which have no relationship to the subject-matter of the Lohrs' claims and none of which has ever been invoked with respect to Medtronic's Model 4011 pacemaker lead. The Lohrs, however, look to the text of section 360k(a), under which preemption occurs only when a state medical device requirement *is* different from, or in addition to, a federal device requirement, and then only where the federal requirement is applicable, not *potentially* applicable, to the device in question.

See U.S. Br. 23; *see also* 43 Fed. Reg. 18661, 18662 (May 2, 1978)("[t]he phrase 'or in addition to, any requirement applicable under this Act to the device' means that an FDA requirement must exist before preemption can occur").

Further, Medtronic fixates on one word—"requirement"—in 21 U.S.C. 360k(a). The Lohrs, however, read that word as part of the sentence in which Congress placed it, in conjunction with its companion provision, 21 U.S.C. 360k(b), and as part of the entire statute, including 21 U.S.C. 360h(d), which preserves state-law damages liability and which is meaningless if section 360k(a) preempts all state tort law in medical device cases.

To be sure, the Lohrs do not ignore the history and purpose of the MDA because "[t]he ultimate question in each [preemption] case is one of Congress's intent, as revealed by the text, structure, purposes, and subject matter of the statute involved." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 545 (1992)(Scalia, J., concurring in the judgment in part and dissenting in part)(citations omitted). The MDA was enacted against a backdrop of serious device failures in which tort litigation played an important role expressly acknowledged by Congress, *see, e.g.*, H.R. Rep. 853, 94th Cong., 2d Sess. 8 (1976)("*House Report*"); neither the text of the MDA nor the debate leading to its passage even hints that Congress was providing device manufacturers with tort immunity; and the legislative history of the MDA refers *solely* to the preemption of positive state law, not tort law. *See id.* at 45-46.

Medtronic's only response is that Congress *might* have eliminated state tort law if it had given that topic any thought. "Members of Congress thinking rationally," Medtronic contends, "could easily conclude" that, in the interest of uniformity, it would be best to eliminate all compensation for harms caused by faulty medical devices. Med. Resp. Br. 3-4. Whether a rational

Congress "could" come to such a conclusion is doubtful; that the 94th Congress did *not* come to such a conclusion is beyond debate. There is *no* evidence, let alone the crystal clear textual evidence that this Court's precedents require, *Hillsborough County v. Automated Medical Labs., Inc.*, 471 U.S. 707, 715 (1985), for the wholesale preemption of state tort law that Medtronic seeks here.

Medtronic asserts that this Court has frequently countenanced preemption of state tort law by federal legislation that does not provide a damages remedy; in fact, *no* decisions of this Court stand for that proposition. The precedents cited by Medtronic, *see* Med. Resp. Br. 5, concern preemption of state law where a federal statute—like the Jones Act or ERISA—*does* provide a private right of action for damages, although not always precisely the same relief otherwise available under state law. There should be no mistake about the unprecedented result sought by Medtronic: elimination of *all* damages remedies for consumers injured by medical devices, a result at odds with the text, structure, history, and purpose of the MDA.[1]

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[1] Medtronic asserts that 21 U.S.C. 360h(b)—which, the FDA informs us, has *never* been invoked in the 20-year history of the MDA—provides a federal damages remedy that would enable Lora Lohr to recover for her injuries. Med. Resp. Br. 5 n.5. Contrary to Medtronic's claim, remedies under section 360h are wholly within the FDA's discretion and *cannot* be invoked by consumers. Moreover, for persons already injured by medical devices (*i.e.*, tort plaintiffs), section 360h(b) could only provide a refund of the device's purchase price. *See* 21 U.S.C. 360h(b)(2)(C). Thus, despite Medtronic's assertion to the contrary, the "reasonable and foreseeable expenses ... incurred in availing [her]self of that remedy," *id.* 360h(b)(3), would not include Ms. Lohr's medical expenses, let alone her lost wages, future medical care, physical pain and scarring, Mr. Lohr's loss of consortium, and other actual damages. *See* Complaint, ¶¶ 2, 15-16, RE 2, 4. Medtronic's claim that section 360h(b) provides a rationale for the elimination of state tort law is all the more absurd in light of 21 U.S.C. 360h(d)(discussed *infra* at 10), which *preserves* state-law damages liability even

(continued...)

In its brief as cross-respondent, Medtronic argues that (1) section 360k(a) preempts damages actions; (2) the MDA contains "requirements" that preempt the Lohrs' failure-to-warn and manufacturing-defect claims; and (3) the Lohrs' damages claims are preempted under section 360k(a) even if they are based on the very federal standards that Medtronic claims have preemptive effect. None of Medtronic's contentions is correct.

ARGUMENT

I. 21 U.S.C. 360k(a) DOES NOT PREEMPT DAMAGES CLAIMS.

In maintaining that damages actions are within the reach of 21 U.S.C. 360k(a), Medtronic wrongly accuses the Lohrs of rearguing issues resolved by the Court in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). Although the word "requirement" appears in one of the statutes at issue in *Cipollone* and in section 360k(a), nothing else about the text, structure, or history of the two provisions is alike, and all indications are that damages actions are not preempted by section 360k(a). *See* Lohr Open. Br. 16-34; Lohr Resp. Br. 8-15. We reply here only to the new arguments made by Medtronic and by the Solicitor General.

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[1](...continued)
after a manufacturer has complied with a refund or repair order. *See also English v. General Electric Co.*, 496 U.S. 72, 75-76 & n.2, 87-90 (1990)(federal administrative remedy for "whistle-blowers" providing back pay, compensatory damages, attorney's fees and costs, and judicial review in federal court, did not preempt state-law tort claim for wrongful discharge because "[o]rdinarily, the mere existence of a federal regulatory or enforcement scheme, even one as detailed as [this one], does not by itself imply pre-emption of state remedies").

A. *Damages Claims Do Not Impose Requirements "With Respect To A Device."*

Section 360k(a) preempts only state-law requirements "with respect to a device." While device requirements contained in state statutes, regulations, and ordinances ordinarily *require* a manufacturer to take some action "with respect to a device," such as removing it from the market, a damages action, if successful, only *requires* the manufacturer to compensate the plaintiff. *See* Lohr Open. Br. 19-21. Damages actions thus "are not requirements 'with respect to a device' within the meaning of section [360k(a)] because they generally pertain ... to persons who manufacture devices or distribute devices..., and not directly to devices. In order for a State provision to be a requirement with respect to a device within the meaning of section [360k(a)]—and thereby a candidate for preemption—it must relate to the device itself." 43 Fed. Reg. at 18663.

Medtronic and the United States do not dispute that, if the phrase "with respect to a device" modifies "requirement," common-law damages actions would not be preempted under section 360k(a). They argue *only* that "the 'with respect to' phrase cannot modify the word 'requirement' because 'requirement' comes *after* that phrase. Rather, the phrase modifies the words ('establish or continue in effect') that come immediately before it." U.S. Br. 17-18; *see* Med. Resp. Br. 14. This interpretation of section 360k(a)'s text is incorrect for several reasons.

First, as a matter of grammar, Medtronic is simply wrong. "With respect to" modifies "requirement" because "with respect to" is an adjectival phrase describing a trait of the noun "requirement." "With respect to" is not an adverbial phrase because it does not describe how a verb is performed. Therefore, it does not modify the verbs "establish" or "continue."

Second, authoritative interpretations of section 360k(a), including the contemporaneous explanation of the House Committee from which section 360k(a) emerged, make clear that "with respect to" modifies "requirement." *See House Report*, at 45. The FDA's regulations and preemption rulings have understood section 360k(a) in this same manner.[2]

Third, contrary to Medtronic's claim, no grammatical rule requires a modifier to come after the word it is modifying, rather than before it. It is not unusual for a modifier to come before the word being modified, as in a portion of the Eleventh Circuit's opinion quoted by the Solicitor General which refers to "preemption-triggering requirements." U.S. Br. 9.

Finally, Medtronic's locution makes no sense. The company claims that Congress needed to modify "establish or continue in effect" with "with respect to a device" to protect a state's ability to enact and enforce laws that address other products in addition to medical devices. But 21 U.S.C. 360k(a)(2) *already* makes clear that the state requirement must "relate" to devices. Moreover, the notion that Congress needed to re-emphasize that the MDA does not preempt laws when they do not regulate medical devices is ludicrous; obviously, the MDA cannot preempt state regulation of, say, lawnmowers or boats.

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[2] *See, e.g.*, 21 C.F.R. 808.1(f); 53 Fed. Reg. 52789, 52790 (Dec. 29, 1988)(Missouri statute prohibiting sale of hearing aids by mail not preempted by federal law because "it is not a requirement with respect to a device" under section 360k(a)); 44 Fed. Reg. 19438, 19439-19440 (Apr. 3, 1979); 43 Fed. Reg. at 18663 ("State laws relating to inspection, registration, and licensing usually are not requirements 'with respect to a device' within the meaning of section [360k] of the act because they generally pertain either to persons who manufacture or distribute devices or to places where devices are manufactured, and not directly to devices").

Compounding its erroneous parsing of the statute, Medtronic—but not the United States—claims that if "with respect to a device" modified "requirement," section 360k(a) could preempt state statutes only if they apply *solely* to medical devices, but not if they regulate more than one type of product, for instance drugs and devices. Med. Resp. Br. 15. Nothing of the sort follows. To use the company's example, state device regulation under a statute that governs both devices and drugs can still be preempted, if the specific regulation at issue *requires* the manufacturer to take action *with respect to a device*. Section 360k(a) does not preempt the Lohrs' damages claims, however, because a favorable judgment will *not*, under any circumstances, require Medtronic to take any action with respect to its Model 4011 pacemaker lead.[3]

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[3] This Court's recent decision in *Morse v. Republican Party of Virginia*, __ U.S. __ (1996), provides further support for the Lohrs' position that damages claims are not preempted because they are not issued by a "State or political subdivision of a State" within the meaning of section 360k(a). *See* Lohr Resp. Br. 10-12. In *Morse*, five members of this Court focused on the purpose and history of the Voting Rights Act to conclude that the phrase "State or political subdivision" brought some activities of political parties within the reach of section 5 of the Act. Opinion of Stevens, J., slip op. at 32; Opinion of Breyer, J., slip op. at 3. Likewise, in this case, the purpose and history of the MDA compel the conclusion that "State or political subdivision of a State" does not include damages verdicts rendered by state and federal juries and judges. *See* Lohr Open. Br. 28-33.

Four members of the Court in *Morse* focused on "the plain meaning" of section 5, as confirmed by other provisions of the Voting Rights Act, to find that "State or political subdivision" applies only to geographical units of state governments, not political parties. Opinion of Thomas, J., slip op. at 1-4; Opinion of Kennedy, J., slip op. at 2, 6. This reading also supports the Lohrs' position in this case, since judges and juries are not units of the state, let alone geographical units. *See* Lohr Resp. Br. 10-12; *see also* Lohr Open. Br. 16-28.

B. The Multiple Uses Of "Requirement" In Section 360k Further Bolster The Lohrs' Position.

1. The parties agree that sections 360k(a)(1) and 360k(a)(2) each use the word "requirement" to describe the kind of positive federal laws that can have preemptive effect—the MDA and regulations thereunder. Those uses of "requirement" plainly exclude damages claims. Section 360k(a) also uses "requirement" a third time to describe actions taken by states concerning medical devices. Because multiple uses of the same word in the same Act—*here, the same sentence*—are ordinarily accorded the same meaning, *Sullivan v. Stroop*, 496 U.S. 478, 484 (1990), state-law "requirements" under section 360k(a) do not go beyond positive law to include damages actions.

Medtronic argues, however, that the statute's federal "requirements" are accompanied by a modifier ("applicable under [the FDCA] to the device"), while the state "requirements" are not. But it is much more logical for Congress to have omitted the modifiers for state requirements as unnecessary because of the rule of construction on which the Lohrs rely, namely, that unless Congress provides to the contrary, the same word means the same thing throughout an Act. Thus, there is no reason to believe that the range of state law subject to preemption is any different from the range of federal law given preemptive effect.[4]

2. Medtronic's interpretation of section 360k(b) is similarly flawed. The company concedes that the texts of sections 360k(a) and 360k(b) are coextensive—that is, that anything preempted

[4] This conclusion is buttressed by the legislative history, which refers *only* to state statutes and regulations as candidates for preemption, *House Report*, at 45-46, and the FDA's regulations and regulatory commentary, which make repeated references to the preemption of state positive law, but do not mention preemption of state tort law. *See* Lohr Open. Br. at 25-27.

under 360k(a) can be exempted from preemption under 360k(b)—and that it would be "very difficult" to obtain an exemption for damages actions under section 360k(b). Med. Resp. Br. 16. It then argues, however, in contradiction to its concessions, that perhaps Congress (without saying so) did not actually intend to permit exemptions for damages claims. *Id.* Thus, in Medtronic's view, preemption of damages claims is a one-way street: all claims would be preempted, but none could be exempted. However, according *less* protection from the incursions of federal law to damages claims than to positive law stands this Court's jurisprudence on its head. The Court has consistently held, in light of the fundamental differences between direct state regulation and tort compensation, that preemption of tort remedies occurs only where the text or structure of the Act unmistakably demands that result. *See, e.g., Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

Moreover, Medtronic provides no rational basis for Congress to have used the same "requirements" language in sections 360k(a) and 360k(b) if it intended the scope of the two sections to be dramatically different. Nor does the company explain how such a scheme can be squared with the FDA's regulations, 21 C.F.R. 808.1(d)(6)(ii), 808.5(b)(2), 808.20(a), 808.20(c)(1), which indicate that sections 360k(a) and 360k(b) are co-extensive and refer only to statutes, regulations, and ordinances as candidates for preemption and exemption from preemption. *See* Lohr Open. Br. 25-27. The only reasonable explanation of the whole provision is the one demanded by its text, structure, and purpose: Sections 360k(a) and 360k(b) encompass the same "requirements," and neither includes state-law damages actions.

C. Section 360h(d) Further Demonstrates That Damages Claims Are Not Preempted.

Under 21 U.S.C. 360h(d), "compliance with an [FDA] order" under section 360h directing a manufacturer to issue a notification, or to repair, replace, or reimburse the purchase price of a device, "shall not relieve any person from liability under ... State law." Medtronic argues that this provision has "nothing to do with tort liability" and applies only to contract actions among manufacturers and their distributors and suppliers. Med. Resp. Br. 18 & n.18. But section 360h plainly applies to device users, *i.e.*, potential tort plaintiffs. For example, 21 U.S.C. 360h(b)—which authorizes the FDA to order device repair and replacement—concerns costs incurred by patients. *E.g.*, *id.* 360h(b)(2)(C); *see House Report*, at 23. And 21 U.S.C. 360h(a)(2) authorizes notification of device risks to "individuals subject to the risk"—device consumers. Thus, Medtronic offers no explanation of how elimination of all tort liability can be squared with the text of section 360h(d)—which preserves state-law claims for damages, even *after* the FDA has ordered a manufacturer to provide a notification, repair, or refund.[5]

[5] The presence of 21 U.S.C. 360h(d) further distinguishes this case from *Cipollone*, where the plurality relied on the *absence* of a savings provision as evidence that the statute at issue there preempts *some* damages actions. *Cipollone*, 505 U.S. at 523 n.22. *Cipollone* also noted that the savings provision of the Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. 4406—whose wording is similar to section 360h(d)—broadly preserves damages actions. *Cipollone*, 505 U.S. at 518; *see also id.* at 537 n.2 (separate opinion).

II. EVEN IF SECTION 360k(a) PREEMPTED SOME DAMAGES CLAIMS, IT WOULD NOT PREEMPT THE LOHRS' FAILURE-TO-WARN AND MANUFACTURING-DEFECT CLAIMS.

A. The Lohrs' Claims Are Not Preempted Because The Applicable Federal Requirements Are Neither Device-Specific Nor Subject-Specific.

Under 21 U.S.C. 360k(a), and its implementing regulation, 21 C.F.R. 808.1(d), for preemption to occur, a federal requirement must address the same subject matter and the same type of device as the relevant state-law requirement. *See* Lohr Open. Br. 39-44. Medtronic does not dispute that the Lohrs' claims are not preempted under section 808.1(d), but asserts that the regulation is not a valid interpretation of section 360k(a). We have previously shown that the FDA regulation is a reasonable interpretation of section 360k(a) that is entitled to deference. *See id.* 40-42; Lohr Resp. Br. 20-22. One point bears emphasis here because it demonstrates the fallacy of Medtronic's position.

Other than an isolated claim that *any* federal requirement preempts *all* state requirements (Med. Resp. Br. 19), the thrust of Medtronic's position is that state law pertaining to particular subject matters is preempted because the FDA regulates, or at least has the power to regulate, those same subject matters. (For instance, the company argues that the good manufacturing practice guidelines preempt all state law concerning device manufacture.) Although, as shown below, Medtronic's approach sweeps far too broadly, the critical point here is that Medtronic itself recognizes that section 360k(a) calls for a subject-matter linkage between the preempting federal requirements and the preempted state requirements, *precisely as 21 C.F.R. 808.1(d) demands.*

Once Medtronic makes that concession, it cannot plausibly contest the validity of 21 C.F.R. 808.1(d) or ignore its implications for the proper construction of the MDA. Section 808.1(d) defines the fit between the state and federal regulations that the text of section 360k(a) demands and insures that the federal requirement concerns the same feature of the medical device (subject-matter specificity) at the same level of generality (device-specificity) as the state requirement. Because no federal requirements demand specific warnings or manufacturing processes for pacemaker leads, the Lohrs' claims are not preempted.

B. None Of The Provisions Of Federal Law Relied On By Medtronic Preempts The Lohrs' Claims.

As shown above, under 21 C.F.R. 808.1(d), the Lohrs' claims are not preempted. Nevertheless, Medtronic argues that the general federal rules regarding device labeling and manufacturing preempt the Lohrs' claims. Even if section 808.1(d) is not dispositive, none of the company's contentions is correct.

1. The Failure-To-Warn Claim.

In urging preemption of the Lohrs' failure-to-warn claim, Medtronic relies chiefly on the FDA's labeling rules for prescription devices. Those rules do not preempt the Lohrs' claim for several reasons.

First, the regulation on which Medtronic relies is not "different from, or in addition to" the Lohr's claim. Under 21 C.F.R. 801.109(c), prescription device labels must contain "any relevant hazards, contraindications, side effects, and precautions." Medtronic attempts to contrast this policy with the Florida common-law duty to provide "fair and adequate warnings" of a product's dangers (Med. Resp. Br. 29), but that duty is obviously not at odds with the federal standard. The company complains that Florida law "could" require warnings that the federal requirement

does not because federal labels need not contain warnings of which doctors are "commonly aware." *Id.* But that general standard is identical to the Florida common-law standard, under which "[a] manufacturer is not compelled to warn knowledgeable [users] of the dangers of which the [user] either knows or should be aware." *Loughan v. Firestone Tire & Rubber Co.*, 749 F.2d 1519, 1525 (11th Cir. 1985)(*quoting Perez v. National Presto Indus., Inc.*, 431 So.2d 667, 669 (Fla. App. 1983)); *cf.* Fla. Admin. Code Ann. 10D-45.043(5)(labels need not provide directions "with respect to common uses, adequate directions for which are known by the ordinary individual").

In any event, "the mere possibility" of conflict with a federal requirement—the basis on which Medtronic urges preemption here—is not enough: Section 360k(a) preempts only where state law "'*is* different from or in addition to' federal requirement." U.S. Br. 23; *see Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982)("The existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute"). Indeed, the facts of this case demonstrate the wisdom of the Court's rule that preemption must be based on reality, not conjecture: Doctors could not possibly be "commonly aware" of the details of Medtronic's pacemaker lead failures unless they were warned of them, and thus such warnings would have been completely consistent with federal law.

Second, the labeling regulations do not preempt the Lohrs' claim because, under those rules, manufacturers are permitted to augment their labels to enhance safety or to warn of prior product failures. Moreover, the section 510(k) notification process did not require approval of the Model 4011 label or require that it contain any particular statements, just as nothing in the regulations bars a manufacturer from changing its label for a 510(k) product. *See*

generally 21 C.F.R. Part 807. Indeed, *even for devices that have received premarket approval*, manufacturers are expressly permitted to make labeling changes that add or strengthen contraindications and warnings or otherwise enhance consumer safety *without* prior FDA approval. 21 C.F.R. 814.39(d)(2)(i)-(iv). Thus, the Lohrs' duty-to-warn claims are not "different from, or in addition to" applicable FDA labeling rules.

Finally, as the United States has shown (U.S. Br. 27)—but Medtronic has ignored—the FDA's labeling rules do not impose any requirements on modes of communication other than labeling. Even in *Cipollone*, where specific congressionally-mandated label warnings were the centerpiece of a federal law that preempted any "requirement or prohibition based on smoking and health ... imposed under State law with respect to the advertising or promotion of [properly labeled cigarette] packages," 505 U.S. at 515, this Court found no preemption of failure-to-warn "claims that rely solely on [the manufacturer's] ... actions unrelated to advertising or promotion." *Id.* at 524-25. Thus, at a minimum, the MDA does not preempt a claim that Ms. Lohr and her physicians should have been warned by means other than the product label.[6]

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[6] Medtronic makes two other bids for preemption of the failure-to-warn claim. First, the company relies on FDA *authority* to take certain actions, some of which are unrelated to labeling (*e.g.*, authority to seize products), and *none* of which the FDA has taken concerning the Model 4011 lead. Med. Resp. Br. 24. Medtronic claims that the FDA has "exclusive authority" under 21 U.S.C. 360h(a) to notify the public about device hazards (Medtronic Br. 28 n.29), but nothing in the text makes the FDA's role "exclusive." In fact, the FDA ruled in a formal advisory opinion that a suit seeking a worldwide notification to device users under state common law was not preempted. *See* Lohr Open. Br., App. 12a-13a. In addition, the agency has formally advised states that their laws granting "authority to disseminate information for the health and safety of" (continued...)

2. The Manufacturing-Defect Claim.

Although Medtronic concedes that there are no MDA requirements relating specifically to the manufacture of pacemaker leads, it nevertheless argues that the federal good manufacturing practice rules ("GMPs")—applicable to virtually all medical devices—preempt the Lohrs' manufacturing-defect claim. The Lohrs' opening brief (at 43-44) showed that, because the MDA's regulation of device manufacture is drawn in such general terms, "state common-law standards governing defective manufacture ... are [not] different from, or in addition to, the applicable GMPs or any other federal requirements." U.S. Br. 23. We rely on our opening brief and add only three points in reply to Medtronic.

First, Medtronic's principal claim is that the Florida common-law duty to produce a non-defective product is preempted because that duty is satisfied only by proof of a dangerous defect,

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[6](...continued)
medical device users are not preempted. 45 Fed. Reg. 67321, 67322 (Oct. 10, 1980); *see, e.g.*, Cal. Health & Safety Code 110175; Fla. Stat. Ann. 499.055(2). And, in any event, federal authority that has not been invoked cannot preempt state law. *Freightliner Corp. v. Myrick*, 115 S. Ct. 1483, 1486 (1995).

Second, Medtronic confuses the *submission* of proposed labeling in a 510(k) notification with FDA *approval* of labeling, which, as the United States notes, does not occur for devices marketed under section 510(k). *See* U.S. Br. 28. Medtronic's 510(k) notification was supposed to contain labeling "sufficient to describe the device, its intended use, and the directions for its use" because that information helps show "whether or not the device is substantially equivalent to a device in commercial distribution." 21 C.F.R. 807.87(e), (k). Labeling is useful in assessing substantial equivalence because the FDA does *not* require submission of a device specimen or any clinical data about how the device actually performs. *See* Kahan, *Premarket Approval Versus Premarket Notification: Different Routes to the Same Market*, 39 Food Drug Cosm. L.J. 510, 516 (1984)("a 510(k) applicant conceptually need not even have an actual device in existence")(quoting testimony of FDA Commissioner to that effect). Because the 510(k) process does not impose *any* requirements with respect to the *content* of labeling, it cannot possibly preempt the Lohrs' failure-to-warn claim.

while the GMPs can be violated even in the absence of such a danger. Med. Resp. Br. 36. But the fact that the Florida common-law duty may be narrower than that under the GMPs does not make the Lohrs' claims "different from, or in addition to" the GMPs, and certainly does not pose any threat to federal law, which is the rationale for preemption in the first place.

Second, despite Medtronic's citation to numerous GMP rules (*id.* at 33), the actual content of those rules is conspicuously absent from its brief. The Lohrs' opening brief (at 44-45) discussed some of the GMPs, showing that they are general guidelines concerning the manufacture of any consumer product and thus could not possibly be at odds with the Lohrs' manufacturing-defect claim. *See also* U.S. Br. 24. For example, a claim that the Model 4011 was not manufactured to specifications could hardly be "different from, or in addition to" GMP rules on that topic: that testing of devices "be based on an acceptable statistical rationale," 21 C.F.R. 820.160, and that "any failure" of a device to "meet performance specifications be investigated." *Id.* 820.162. The generality of the GMPs not only demonstrates that the Lohrs' claim is not "different from, or in addition to" the GMPs, but also underscores the practical wisdom of the FDA's insistence in 21 C.F.R. 808.1(d) that federal requirements be specific if they are to have preemptive effect. *See* U.S. Br. 24-25.

Finally, Medtronic makes no attempt to show that the Lohrs' manufacturing-defect claim "*is* different from, or in addition to" any particular GMP or any federal device-manufacturing standard, as section 360k(a) demands. U.S. Br. 23. "[T]he mere possibility that a tort plaintiff's defective-manufacture claim might, if successful, effectively be based on a requirement that a device manufacturer do something 'different from, or in addition to,' something required by the general standards enunciated in the

GMPs" does not warrant preemption. *Id.* Accordingly, the Lohrs' manufacturing-defect claim is not preempted.

III. THE LOHRS' CLAIMS ARE NOT PREEMPTED INSOFAR AS THEY RELY ON FEDERAL STANDARDS.

Medtronic maintains that even if the Lohrs' claims are based on the same substantive standards as those provided by the MDA, their claims are preempted. Whatever its other limits, however, section 360k(a) preempts only state device laws that are "different from, or in addition to" applicable federal requirements. For instance, a state labeling regulation for tampons is *different from* the federally-mandated label, *see* 21 C.F.R. 801.430, if the state regulation requires the manufacturer to alter the label's wording in some substantial manner. Similarly, the state regulation would be *in addition to* the federal label if it required that the label contain new material, not contained in 21 C.F.R. 801.430. Yet under Medtronic's reading of section 360k(a), no state could take enforcement action, even if based solely on a manufacturer's failure to use the mandatory tampon label, and no jury could award damages to an injured plaintiff as a result of that failure. Such a result flies in the face of section 360k(a), which preempts state law that imposes requirements "different from, or in addition to"—not the same as—requirements imposed by the MDA.

Medtronic makes several attempts to avoid the statute's plain meaning. First, the company says that *all* state law is "in addition to" federal law. If the mere *existence* of state device laws were itself "in addition to" federal law, however, section 360k(a) would have been written to say simply that "all State law concerning medical devices is preempted."

Second, Medtronic relies on language from preemption provisions of medical device legislation that did *not* become law,

in particular the Senate version of the MDA which preempted certain state device laws unless their "requirements [were] identical to the Federal requirements." S. 510, 94th Cong., 1st Sess. § 704 (1975). If anything, "identical" is *narrower* than "different from, or in addition to," because it arguably demands that the state law be the same as the federal law in its exact wording, as well as in its application. *Compare* 21 C.F.R. 808.1(d)(2).

Medtronic nonetheless claims that only the language in the Senate bill could have preserved state device requirements that are the same as federal requirements. However, if Medtronic is correct that mere state enforcement of federal standards amounts to imposition of a requirement "in addition to" federal requirements, then such enforcement would also entail imposition of a requirement non-"identical" to federal requirements. In fact, with respect to both the Senate bill and to section 360k(a) as enacted, the text is clear that state law that applies substantive standards fully consistent with federal law is not preempted.

Finally, lacking any anchor in section 360k(a), Medtronic argues that courts—particularly "state judges"—will be unable to apply federal law and will preserve claims that ought to be preempted. Med. Resp. Br. 44. Medtronic's distrust of state judiciaries not only defies the presumption against preemption, but is hostile to federalism itself, a central postulate of which is that state and federal courts have co-equal responsibility for enforcing federal law. *Gulf Offshore Co. v. Mobil Oil*, 453 U.S. 473, 477-78 (1981); *Atlantic Coast Line R.R. v. Brotherhood of Locomotive Eng'rs*, 398 U.S. 281, 295-96 (1970); *see* Wright, *Federal Courts* 268-73 (4th ed. 1983). For these reasons, among others, there is generally no preemption where the "case concerns only the state's mechanisms for enforcing a statute identical with that of the federal government." *California v. Zook*, 336 U.S. 725, 736 (1948).

Moreover, Medtronic points to no problems in states where local authorities enforce federal medical device standards. *See, e.g.*, Cal. Health & Safety Code 110105, 111245, 111325, 111550(a); Fla. Stat. Ann. 499.002(2),(3), 499.013(2)(d)1; N.Y. Educ. Law 6802(13); N.Y. Gen. Bus. Law 640(1)(d). Nor is it the case that the regulation of foods, drugs, and cosmetics is in chaos, even though it has long been held that state misbranding and similar laws are not preempted if they are consistent with federal standards. *See, e.g., Corn Products Refining Co. v. Eddy*, 249 U.S. 427 (1919).

This result is also compelled by the FDA's regulations and other authoritative statements, which are entitled to deference. *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 842-45 (1984). After considering the very arguments Medtronic raises here, the FDA determined that section 360k(a) "does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act." 21 C.F.R. 808.1(d)(2). The FDA explained that it:

> cannot accept the argument that an identical State or local requirement is preempted because it is "in addition to" the FDA requirement. Such an interpretation ... renders meaningless the "different from" language ... because under this theory any State and local requirement would be preempted whether or not it was actually "different from" an FDA requirement.

43 Fed. Reg. at 18663; *accord Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1457 (9th Cir. 1995).

Moreover, the FDA has consistently encouraged enforcement of state device laws that do no more than incorporate federal standards. For instance, the agency ruled that California's GMPs

are not preempted because they simply adopt the federal GMPs. The FDA rejected complaints, identical to those of Medtronic, that "the State *may* interpret or apply the [federal] requirement in a different manner." 45 Fed. Reg. at 67322 (emphasis added); *compare* 21 U.S.C. 360k(a)(state requirement preempted if it "*is* different from, or in addition to" applicable federal requirement)(emphasis added). Similarly, the FDA held that state labeling requirements, general enforcement regulations, and state statutes permitting the seizure and embargo of devices are *not* preempted if the substantive standards under which they are enforced do not differ from federal standards. 45 Fed. Reg. at 67322. And the agency urged the "States [to] assist in enforcing the FDA hearing aid regulations by adopting requirements identical to the FDA requirements." *Id.* at 67327. Given these rulings, which enable the states to remove devices from the market, it is difficult to conceive how the Lohrs' damages claims could be preempted if they are premised on substantive duties consistent with applicable federal requirements.[7]

CONCLUSION

For these reasons and those set forth in the Lohrs' previously-filed briefs, the Court should hold that none of the Lohrs' claims is preempted.

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[7] Medtronic faults 21 C.F.R. 808.1(d)(2) for providing that state laws are not preempted if they are "*substantially* identical" to federal requirements. Med. Resp. Br. 39 n.38. But the FDA has interpreted "different from, or in addition to" in this manner so that it can consider how the state "requirement is interpreted and applied, not merely the literal language of the applicable statute." 43 Fed. Reg. at 18663. This FDA regulation prevents the elevation of form over substance and is certainly a "permissible construction" of section 360k(a). *Chevron*, 467 U.S. at 843.

Respectfully submitted,

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April 16, 1996